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(54) **Method for manufacturing a folding balloon catheter**

Verfahren zur Herstellung eines faltbaren Ballonkatheters

Procédé de fabrication d'un cathéter à ballonnet pliable

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Description

FIELD OF THE INVENTION

The present invention relates to a method for manufacturing an angioplasty device which employs a folding balloon catheter having atherotomes mounted along the outer surface of the balloon.

BACKGROUND OF THE INVENTION

Blockage of human arteries is a widespread malady and, as such, represents a significant health concern. Blockages reducing blood flow through the coronary arteries to the heart can cause heart attacks, while blockages reducing blood flow through the arteries to the brain can cause strokes. Similarly, arterial blockages reducing blood flow through arteries to other parts of the body can produce grave consequences in an affected organ or limb.

The build-up of atherosclerotic plaque is a chief cause of blockages, termed stenoses, which reduce blood flow through the arteries. Consequently, several methods have been introduced to alleviate the effects of plaque build-up restricting the artery. One such method is a procedure termed angioplasty, which uses an inflatable device positioned at the stenosis to dilate the artery. A typical angioplasty device is disclosed in U.S. Patent No. 4,896,669 to Bhate et al. The angioplasty device of Bhate et al includes an inflatable balloon which is attached to the distal end of a hollow catheter tube. The proximal end of the catheter tube is attached to a fluid source.

To treat an arterial stenosis, the balloon of Bhate et al is introduced into the artery in a deflated state and guided through the artery over a guide wire to a position adjacent the stenosis. Fluid from the fluid source is then infused into the balloon via the catheter tube to inflate the balloon. As the balloon expands, it presses against the arterial wall in the region of the stenosis, dilating the artery at the stenosis and restoring it to a sufficient size for adequate blood flow therethrough. The balloon is then deflated and removed from the artery, thereby completing the treatment.

A desirable feature of a balloon catheter is that the balloon be able to assume a neatly folded and compact configuration when it is in the deflated state. This is so in order to facilitate the insertion and passage of the balloon catheter through the blood vessel. Passage of the balloon through the vessel becomes even more difficult to accomplish if the structure of the balloon catheter is relatively complicated. Specifically, it has been proposed that a cutting element be used in concert with the operation of the balloon to facilitate dilation of the vessel at the stenosis. As can be easily appreciated, safety also becomes an issue of concern when cutting elements are included. Even more so when these cutting elements are mounted directly onto the outer surface of the balloon.

FR-A-2 529 083 discloses a balloon catheter in which the balloon is provided with three angularly spaced rigid reinforcing bands which extend along the length of the balloon. When the balloon is deflated, the reinforcing bands maintain their position and the portions of the balloon between the bands collaps inwardly.

In light of the above, it is an object of the present invention to provide a method for manufacturing a folding balloon catheter having a balloon with a predictable folded configuration when the balloon is deflated. It is another object of the present invention to provide a method for manufacturing a folding balloon catheter having atherotomes mounted on the outer surface of the balloon. It is yet another object of the present invention to provide a method for manufacturing a folding balloon catheter having atherotomes mounted on the balloon which is relatively easy to perform and comparatively cost effective.

SUMMARY OF THE INVENTION

The present invention is a method for manufacturing a balloon catheter which includes a plurality of elongated atherotomes that are attached to the outer surface of the balloon along predetermined crease lines. The device, as manufactured, is useful in an angioplasty procedure to incise stenotic tissue in a blood vessel, and to thereby facilitate dilation of the vessel as the balloon is expanded.

In accordance with the present invention, the method for manufacturing a balloon catheter is initiated by positioning a substantially cylindrical shaped balloon membrane over a portion of a hollow catheter tube. More specifically, the ends of the balloon membrane are inwardly tapered and the portion of the catheter tube over which the balloon membrane is positioned, is formed with a fluid port. The fluid port is thus located intermediate the ends of the balloon membrane and the ends are then fixedly attached to the catheter tube. This creates a fluid chamber between the catheter tube and the wall of the balloon membrane and fluid communication is established between this chamber and the catheter tube through the fluid port. Accordingly, fluid flow into and out of the chamber through the fluid port will respectively inflate and deflate the balloon.

With the balloon inflated, a thin layer of a curable elastomer adhesive, such as urethane, is applied at selected locations on the outside of the balloon wall. This creates adhesive patches on the surface of the balloon where the atherotomes are to be attached. As contemplated by the present invention, each atherotome is an elongated structure that includes a blade with a cutting edge. The blade itself is embedded in an elastomer base that will adhere to the patch of elastomer adhesive on the balloon. As further contemplated by the present invention, when the atherotome is attached to the balloon, the cutting edge of the atherotome faces radially outward from the axis of the balloon catheter. Consequently, each atherotome is oriented substantially paral-

lel to the catheter tube and each atherotome extends for a substantial distance along the length of the balloon.

Once the atherotomes have been attached to the balloon as desired, the balloon is heated to a predetermined partial curing temperature and maintained at that temperature for a predetermined period of time. This partial curing accomplishes an important purpose. After partial curing, the adhesive patches are no longer tacky to the touch and the atherotomes are more securely attached to the balloon.

When partial curing has been completed, the balloon is deflated. Not unexpectedly, as the balloon is deflated, creases and folds or flaps form in the balloon wall. For the present invention it is important that the location of the creases and folds in the balloon be predictable. Specifically, the creases need to he along those portions of the balloon where the atherotomes are attached.

The preferred orientation of the creases, and thus the folds between the creases, is facilitated by using a special folding tool. This tool comprises a body having a central cylindrical aperture. Additionally, the tool has a plurality of linear slots which extend radially from the central aperture. Slidably positioned within each of these slots is a planar member that is inwardly biased by a spring toward the aperture.

For the operation of the special tool, an inflated balloon with attached atherotome is inserted into the aperture of the tool. This is cone after the partial curing step. As so positioned, the cutting edge of each atherotome extends into a respective slot of the special tool and each of the planar members urges inwardly against the cutting edge of a respective atherotome. As the balloon is subsequently deflated, the planar members are moved inwardly to displace the atherotomes toward the center of the aperture. This displacement establishes a folded configuration for the balloon. In this folded configuration, the balloon is creased or furrowed at the locations of the atherotomes, and those portions of the balloon membrane between the creases are folded outwardly to create flaps of balloon membrane material between the atherotomes.

While in the folded configuration, the balloon is heated to a predetermined final curing temperature and is maintained at that temperature for a predetermined final curing time. This step cures all of the balloon membrane and creates a permanent set or memory in the membrane which will cause the balloon to return to its folded configuration whenever the balloon is deflated.

The novel features of this invention, as well as the invention itself, both as to its structure and its operation will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure **1** is a perspective view of a balloon catheter in a separated relationship with a folding tool used in the manufacturing method of the present invention;

Figure 2A is a cross-sectional view of an expanded balloon catheter inserted into the folding tool as seen along line 2-2 in Figure 1 prior to the deflation step in the manufacturing method of the present invention; and

Figure 2B is a cross-sectional view of the balloon catheter in its contracted state as would be seen in Figure 2A after performing the deflation step in the manufacturing method of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention is a multi-step method of manufacturing a folding balloon catheter, such as the balloon catheter shown in Figure 1 and generally designated **10**. In accordance with the present invention, the method for manufacture is initiated by joining a conventional angioplasty balloon **12** with a hollow catheter tube **14**. The balloon **12** is preferably shaped as a hollow tubular structure having a thin outer wall **16**. As seen in Figure 1, the ends **13a** and **13b** of balloon **12** are tapered inwardly. Preferably, the wall **16** of balloon **12** is made of a pliant polymeric material which encloses and defines an interior chamber **17** which is, perhaps, best seen in Figure 2A. Preferably balloon **12** is made of a material well known in the art, such as a biaxially oriented material. The catheter tube **14** is flexible and, like balloon **12**, is preferably formed from a polymeric material. Additionally, catheter tube **14** has a port **26** that is positioned near one end of the tube **14**.

In order to join the balloon **12** to catheter tube **14**, the tube **14** is inserted into balloon **12** to extend through the chamber **17**. Thus, port **26** is positioned within the chamber **17**. The ends **13a** and **13b** of balloon **12** are then sealed to catheter tube **14**. Consequently, any fluid communication with the chamber **17** can only be accomplished from catheter tube **14** through the port **26**. The seal between ends **13a** and **13b** of balloon **12** and catheter tube **14** is effected by any-known bonding technique such as adhesive bonding or thermal bonding. The result is a balloon catheter structure which is further modified according to the steps described hereafter.

With the balloon **12** attached to catheter tube **14**, the balloon **12** is inflated. This is done by infusing a fluid such as air into the balloon chamber **17**, under pressure, which causes the balloon chamber **17** to expand. When balloon **12** is inflated, wall **16** defines a substantially cylindrical surface having tapered ends. A thin layer of an elastomeric adhesive (preferably urethane) is then applied to the exterior surface of the balloon wall **16** at preselected points to form adhesive patches **18**. These patches **18** are preferably elongated and rectan-

gular shape. Further, the patches **18** are preferably aligned to be parallel with the longitudinal axis of the balloon **12** and equidistantly spaced from adjacent patches **18** about the periphery of the balloon. The adhesive for creating the patches **18** is preferably a curable resin such as a polyurethane which is applied in a liquid or semi-liquid state by means such as dipping, spraying or painting.

When initially applied onto the surface of wall **16** of balloon **12**, the adhesive patches **18** are tacky. This makes it possible to mount an atherotome **19** onto each of the patches **18** as desired. In a preferred embodiment of the present invention, at least three atherotomes **19** are mounted onto the balloon **12**. The actual number of atherotomes **19** will, obviously, correspond to the number of patches **18** on balloon **12**, since each atherotome **19** is mounted on a single adhesive patch **18**. In order to make the attachment, each atherotome **19** is firmly embedded into a polyurethane base **21** which dimensionally corresponds in shape to the patch **18**. Preferably, however, the patch **18** is dimensioned somewhat larger than the base **21**. With the bases **21** of atherotomes **19** stuck onto the outer surface of balloon **12**, the balloon catheter **10** is now in set for a partial curing of the adhesive patches **18**.

Partial curing is performed by placing the balloon **12** portion of balloon catheter **10** in an oven (not shown) that has been preheated to a predetermined partial curing temperature. Preferably, partial curing temperature is in the range of between about one hundred and twenty and one hundred and seventy degrees Fahrenheit (120-170°F) (49 - 77°C), and more preferably at a partial curing temperature of about one hundred and sixty degrees Fahrenheit (160°F) (71°C). The balloon catheter **10** is maintained in the oven at the partial curing temperature for a predetermined partial curing time of between about fifteen and forty five minutes and, preferably, for a partial curing time of about one half hour. As a consequence of partial curing, the adhesive patches **18** lose their tackiness, and the atherotomes become fixedly attached to balloon **12**.

The balloon catheter **10** is now in a condition for the additional processing that is necessary to insure the balloon **12** will predictably assume a desired configuration when deflated. Figure 1 shows balloon catheter **10** in position for the deflation and folding steps that follow the partial curing step. Specifically, balloon **12** is shown inflated to its expanded condition with atherotomes **19** mounted on adhesive patches **18**.

As intended for the present invention, the deflation and folding steps in the method of manufacture are performed simultaneously by means of a special folding tool, shown in Figure 1 and generally designated **28**. As shown, tool **28** has a body **30** that is segmented into four identical sections **32 a-d** which are positioned to surround and define a central aperture **34**. As so positioned, sections **32 a-d** establish the slots **36 a-d** which separate adjacent sections **32** from each other. It is to be appreciated that tool **28** shown in Figure 1 is only exemplary. The number of sections **32** which are used to create body **30** will vary depending on the number of atherotomes **19** to be mounted on balloon **12**.

As also shown in Figure 1, a planar member **38** is slidably positioned within each slot **36**. Each of the planar members **38** is a substantially identical stiff metal panel having a pad **40** which is affixed to, and coextensive with, the axial edge **42** of member **38**. Pad **40** is formed from a relatively resilient material, such as an elastomer or a plastic, to cushion its contact with the sharpened cutting edge **44** of each atherotome **19**.

Aperture **34**, slots **36 a-d** and planar members **38 a-d** are dimensioned such that when balloon **12** is in an expanded condition, balloon **12** fits snugly within aperture **34**. As balloon **12** is inserted into aperture **34**, each slot **36** receives one of the cutting edges **44** of atherotome **19**. When initially inserted into the slots **36** the cutting edges **44** of atherotomes **19** do not abut with pad **40** of a planar member **38**.

Attached to the body **30** of tool **28** and associated with each slot **36 a-d** is some means for respectively urging each planar member **38** inwardly toward the central aperture **34**. In one embodiment of the present invention, this urging means is a band spring **46** which is attached to the outside of body **30** substantially perpendicular to slot **36**. Each spring **46** is positioned across one of the slots **36 a-d** to abut the outside edge **48** of the planar member **38** in the particular slot **36**.

For the loading configuration of tool **28**, as shown in Figures 1 and **2**, springs **46** are deformed to bias members **38** inwardly toward the central aperture **34**. Means (not shown) may be further provided for withdrawing planar members **38** away from the central aperture **34** and for maintaining planar members **38** in this loading position.

As indicated above, the deflation and folding steps are performed by first inserting an inflated balloon **12** into the central aperture **34** of tool **28** along the path of dotted lines **50** shown in Figure 1. Referring now to Figure 2A, balloon **12** and catheter tube **14** are shown to be coaxially positioned in the aperture **34** of tool **28**. Once balloon **12** is so positioned, planar members **38** are biased by springs **46** toward central aperture **34**. This causes the pads **40** of planar members **38 a-d** to abut cutting edges **44** of atherotomes **19**. At this point in the process, the fluid pressure inside interior chamber **17** of balloon **12** prevents the biased planar members **38** from collapsing balloon **12**.

Balloon **12** is now collapsed. To do this, the fluid in interior chamber **17** is withdrawn at a controlled rate through port **26** and catheter tube **14**. As shown in Figure 2B, the result is that springs **46** urge planar members **38** toward central aperture **34** to reconfigure the collapsing balloon **12**.

As indicated above, during reconfiguration of the collapsing balloon **12**, planar members **38** drive against the atherotomes **19**. Simultaneously, the wall **16** of balloon **12** is folded to create flaps **54** which are formed between the atherotomes **19**. Additionally, creases **56**

are set into the balloon wall **16** at the location of each adhesive patch **18** and corresponding atherotome **14**. During this step, flaps **54** are established substantially parallel to each other and are aligned with the longitudinal axis of the balloon catheter **10**. The deflation and folding steps are, thus, completed and the balloon **12** is removed from the central aperture **34** of tool **28** in a folded or contracted configuration.

The last step of the present method is the final curing of the balloon **12**. Final curing is performed by placing balloon **12** in an oven (not shown) that has been preheated to a predetermined final curing temperature in a range of between about one hundred and twenty and one hundred and seventy degrees Fahrenheit (120-170 °F) (49 - 77°C), and more preferably at a partial curing temperature of about one hundred and sixty degrees Fahrenheit (160°F) (71°C). The balloon **12** is maintained in the oven at this final curing temperature for a predetermined final curing time of between eight and twelve hours (8-12 hrs). Preferably, this final curing time is of about 8 hours. Thus, it is apparent that the final curing step is distinguishable from the partial curing step in the present case by the length of the curing time, i.e., the final curing time is considerably longer than the partial curing time although the curing temperatures may be the same.

The balloon catheter is now in a suitable condition for its intended use. During the manufacturing steps set forth above, it has happened that the flaps **54** and creases **60** in balloon **12** which are formed during the previously described folding step are rendered permanent by the final curing step. Thus, for subsequent inflations and deflations of balloon **12** the preset flaps **54** and creases **60** enable substantially identical replication of the balloon's configurations when alternating between the expanded and contracted states.

After the balloon catheter **10** of the present invention has been assembled, it can be neatly packaged by performing the following generalized steps. First, after the final cure has been completed, balloon **12** of balloon catheter **10** is inserted into a silicone rubber tube (not shown) while the balloon **12** is still in a deflated configuration. The silicone rubber tube needs to have an inner diameter which is approximately equal to the outer diameter of the collapsed balloon **12** so that the collapsed balloon **12** can fit snugly inside the lumen of the silicone rubber tube. Further, the silicone rubber tube must be sufficiently long so that its ends extend beyond both of the ends **13a** and **13b** of balloon **12**. Next, fluid is infused into interior chamber **17** of the balloon **12** through catheter tube **14** to inflate the balloon **12** inside the silicone rubber tube.

At this point, inflation of the balloon **12** has also expanded the lumen of the silicone rubber tube. With balloon **12** still inside the silicone rubber tube, while the balloon **12** is initially inflated, the ends of silicone rubber tube are pulled apart to contract the lumen of the silicone rubber tube. This contraction of the lumen of the silicone rubber tube forces the balloon **12** to draw down into an extremely compact configuration When balloon **12** is in the compact configuration, balloon catheter **10** can be easily packaged in a retainer tube for storage or shipping.

Claims

1. A method of manufacturing a folding balloon catheter (10) having an elongated balloon (12) enclosing an expandable chamber (17) and a hollow catheter tube (14) attached to the balloon (12) in fluid communication with the chamber (17), the method being characterised by:

   inflating said balloon (12);

   applying a plurality of patches (18) of an elastomeric material to the exterior of said balloon (12);

   mounting an atherotome (19) on each said patch (18) to fixably connect said atherotome (19) to said balloon (12);

   partially curing said inflated balloon (12) by heating said balloon (12) to a predetermined partial curing temperature and maintaining said partial curing temperature for a predetermined partial curing time to establish creases (56) for said balloon (12) at said patches (18);

   collapsing said balloon (12) along said creases (56) to fold said balloon (12) and create flaps (54) between said creases (56) such that said atherotomes (19) are displaced towards the central longitudinal axis of said balloon (12) and said flaps (54) are folded outwardly; and

   curing said collapsed balloon (12) by heating said material to a predetermined final curing temperature and maintaining said final curing temperature for a predetermined final curing time.

2. A method according to Claim 1 wherein said elastomeric material is a synthetic resin.

3. A method according to Claim 1 or 2 wherein said partial curing temperature is substantially equal to said final curing temperature.

4. A method according to Claim 3 wherein said partial curing temperature and said final curing temperature are approximately 71°C (160°F).

5. A method according to any one of the preceding claims wherein said final curing time is substantially greater than said partial curing time.

6. A method according to Claim 5 wherein said partial curing time is approximately 30 minutes and said final curing time is approximately 8 hours.

7. A method according to any one of the preceding claims wherein the balloon (12) is inflated and collapsed by respectively introducing fluid into said

chamber (17) and withdrawing fluid from said chamber (17).

8. A method according to any one of the preceding claims wherein said atherotomes (19) are elongated and are mounted on said balloon (12) substantially parallel to the longitudinal axis of said balloon (12) and wherein each atherotome (19) has a cutting edge (44) facing radially outward from the longitudinal axis of said balloon (12) when said atherotome (19) is mounted in said balloon (12).

9. A method according to any one of the preceding claims wherein said balloon (12) is collapsed to a contracted state by displacing each said atherotome (19) toward the central longitudinal axis of said balloon (12) using a collapsing means (28) opposingly abutting said cutting edge (44) of said atherotome (19).

10. A method according to Claim 9 further comprising the step of positioning said balloon (12) in said collapsing means (28), said collapsing means (28) comprising: a body (30) having an aperture (34) with a slot (36) formed in said body (30) extending radially from said aperture (34) and further wherein a slidable member (38) is positioned within said slot (36) for abutment against said cutting edge (44) of said atherotome (19), said slidable member (38) being urged to press against said atherotome (19) to collapse said balloon (12).

11. A method according to Claim 10 further comprising positioning said cutting edge (44) in said slot (36) in abutment with said slidable member (38) and performing said contracting step by sliding said member (38) toward said aperture (34) to displace said atherotome (19) toward the longitudinal axis of said balloon (12), thereby forming a fold in said wall (16) corresponding to the location of said atherotome (19).

12. A method according to Claim 11 wherein contact between said cutting edge (44) and said member (38) is cushioned by an elastomeric pad (40) affixed to said member (38).

13. A method according to any one of Claims 10 to 12 wherein said slidable member (38) is biased toward said aperture (34).

14. A method according to Claim 11 wherein a fluid is withdrawn from said chamber (17) while sliding said balloon (12).

Patentansprüche

1. Verfahren zur Herstellung eines faltbaren Ballonkatheters (10) mit einem eine aufweitbare Kammer (17) umschließenden, langgestreckten Ballon (12) und einem in Fluidverbindung mit der Kammer (17) am Ballon (12) angebrachten hohlen Katheterschlauch (14), gekennzeichnet durch (folgende Schritte):

Aufblasen des Ballons (12),

Anbringen einer Anzahl von Flecken (18) aus einem elastomeren Material an der Außenseite des Ballons (18),

Montieren oder Anbringen eines Atheroms (atherotome) (19) an jedem der Flecke (18) zwecks fixierbarer Verbindung des Atheroms (19) mit dem Ballon (12),

teilweises Aushärten des aufgeblasenen Ballons (12) durch Erwärmen des Ballons (12) auf eine vorbestimmten Teilaushärtetemperatur und Aufrechterhalten der Teilaushärtetemperatur für eine vorbestimmte Teilaushärtezeit zwecks Erzeugung von Kniffen oder Falten (56) für den (im) Ballon (12) an den Flecken (18),

Zusammendrücken des Ballons (12) längs der Kniffe oder Falten (56), um den Ballon (12) zu falten und zwischen den Kniffen bzw. Falten (56) Laschen (54) zu erzeugen, so daß die Atherome (19) zur zentralen Längsachse des Ballons (12) hin versetzt und die Laschen (54) nach außen gefaltet sind bzw. werden, und

Aushärten des zusammengedrückten Ballons (12) durch Erwärmen des genannten Materials auf eine vorbestimmte Endaushärtetemperatur und Aufrechterhalten der Endaushärtetemperatur für eine vorbestimmte Endaushärtezeit.

2. Verfahren nach Anspruch 1, wobei das elastomere Material ein Kunstharz ist.

3. Verfahren nach Anspruch 1 oder 2, wobei die Teilaushärtetemperatur der Endaushärtetemperatur praktisch gleich ist.

4. Verfahren nach Anspruch 3, wobei die Teilaushärtetemperatur und die Endaushärtetemperatur etwa 71°C (160°F) betragen.

5. Verfahren nach einem der vorangehenden Ansprüche, wobei die Endaushärtezeit wesentlich länger ist als die Teilaushärtezeit.

6. Verfahren nach Anspruch 5, wobei die Teilaushärtezeit etwa 30 min und die Endaushärtezeit etwa 8 h betragen.

7. Verfahren nach einem der vorangehenden Ansprüche, wobei der Ballon (12) aufgeblasen und zusammengedrückt (kollabiert) wird, indem Fluid in die Kammer (17) eingeleitet bzw. Fluid aus der Kammer (17) abgelassen wird.

8. Verfahren nach einem der vorangehenden Ansprüche, wobei die Atherome (19) langgestreckt und am Ballon (12) praktisch parallel zur Längsachse des Ballons (12) angebracht sind und wobei jedes Atherom (19) eine Schneidkante (44) aufweist, die bei im (am) Ballon (12) angebrachtem Atherom (19) von der Längsachse des Ballons (12) radial nach außen weist.

9. Verfahren nach einem der vorangehenden Ansprüche, wobei der Ballon (12) in einen zusammengezogenen Zustand zusammengedrückt (kollabiert) wird, indem jedes Atherom (19) mit Hilfe eines Zusammendrückmittels (28), das sich gegenüberliegend an die Schneidkante (44) des Atheroms (19) anlegt, in Richtung auf die zentrale Längsachse des Ballons (12) verschoben oder verlagert wird.

10. Verfahren nach Anspruch 9, ferner umfassend den Schritt eines Positionierens des Ballons (12) im Zusammendrückmittel (28), welches Zusammendrückmittel (28) umfaßt: einen Körper (30) mit einer Bohrung (34) mit einem im Körper (30) geformten und von der Bohrung (34) (aus) radial verlaufenden Schlitz (36), wobei ferner im Schlitz (36) ein verschiebbares Element (38) für Anlage gegen die Schneidkante (44) des Atheroms (19) positioniert ist, welches verschiebbare Element (38) zum Anpressen gegen das Atherom (19), um den Ballon (12) zusammenzudrücken bzw. zum Kollabieren zu bringen, druckbeaufschlagt ist.

11. Verfahren nach Anspruch 10, ferner umfassend: Positionieren der Schneidkante (44) im Schlitz (36) in Anlage am verschiebbaren Element (38) und Durchführen des Zusammendrückschritts durch Verschieben des Elements (38) in Richtung auf die Bohrung (34), um das Atherom (19) zur Längsachse des Ballons (12) hin zu verschieben und damit in der Wand (16) eine Falte entsprechend der Lage des Atheroms (19) zu formen.

12. Verfahren nach Anspruch 11, wobei eine Berührung zwischen der Schneidkante (44) und dem Element (38) durch einen am Element (38) befestigten elastomeren Belag (40) abgepuffert wird.

13. Verfahren nach einem der Ansprüche 10 bis 12, wobei das verschiebbare Element (38) in Richtung auf die Bohrung (34) vorbelastet ist.

14. Verfahren nach Anspruch 11, wobei während eines Verschiebens des Ballons (12) ein Fluid aus der Kammer (17) abgelassen wird.

Revendications

1. Procédé de fabrication d'un cathéter à ballonnet pliable (10) comportant un ballonnet allongé (12) entourant une chambre expansible (17) et un tube creux de cathéter (14) fixé au ballonnet (12) en communication par fluide avec la chambre (17), le procédé étant caractérisé par :

   le gonflement dudit ballonnet (12) ;

   l'application d'une pluralité de pastilles (18) en élastomère sur l'extérieur dudit ballonnet (12) ;

   le montage d'un athérotome (19) sur chacune desdites pastilles (18) pour relier de manière fixable ledit athérotome (19) audit ballonnet (12) ;

   la cuisson partielle dudit ballonnet (12) gonflé en chauffant ledit ballonnet (12) à une température prédéterminée de cuisson partielle et en maintenant ladite température de cuisson partielle pendant un temps prédéterminé de cuisson partielle pour créer des plis (56) pour ledit ballonnet (12) au niveau desdites pastilles (18) ;

   l'aplatissement dudit ballonnet (12) le long desdits plis (56) pour plier ledit ballonnet (12) et créer des rabats (54) entre lesdits plis (56) de sorte que lesdits athérotomes (19) soient déplacés vers l'axe longitudinal central dudit ballonnet (12) et que lesdits rabats (54) soient pliés vers l'extérieur ; et

   la cuisson dudit ballonnet (12) replié en chauffant ledit matériau à une température prédéterminée de cuisson finale et en maintenant ladite température de cuisson finale pendant un temps prédéterminé de cuisson finale.

2. Procédé selon la revendication 1, dans lequel ledit élastomère est une résine synthétique.

3. Procédé selon la revendication 1 ou 2, dans lequel ladite température de cuisson partielle est sensiblement égale à ladite température de cuisson finale.

4. Procédé selon la revendication 3, dans lequel ladite température de cuisson partielle et ladite température de cuisson finale sont approximativement de 71°C (160°F).

5. Procédé selon l'une quelconque des revendications précédentes, dans lequel ledit temps de cuisson finale est sensiblement plus grand que ledit temps de cuisson partielle.

6. Procédé selon la revendication 5, dans lequel ledit temps de cuisson partielle est approximativement de 30 minutes et ledit temps de cuisson finale est approximativement de 8 heures.

7. Procédé selon l'une quelconque des revendications précédentes, dans lequel le ballonnet (12) est gonflé et replié en introduisant du fluide dans ladite

chambre (17) et en retirant le fluide de ladite chambre (17), respectivement.

8. Procédé selon l'une quelconque des revendications précédentes, dans lequel lesdits athérotomes (19) sont allongés et sont montés sur ledit ballonnet (12), sensiblement parallèles à l'axe longitudinal dudit ballonnet (12), et dans lequel chaque athérotome (19) présente un côté (44) tranchant tourné radialement vers l'extérieur de l'axe longitudinal dudit ballonnet (12) quand ledit athérotome (19) est monté dans ledit ballonnet (12).

9. Procédé selon l'une quelconque des revendications précédentes, dans lequel ledit ballonnet (12) est replié en un état contracté en déplaçant chacun desdits athérotomes (19) vers l'axe longitudinal central dudit ballonnet (12) en utilisant des moyens de pliage (28) contigus, de manière opposée, audit côté (44) tranchant dudit athérotome (19).

10. Procédé selon la revendication 9, comprenant de plus l'étape consistant à positionner ledit ballonnet (12) dans lesdits moyens de pliage (28), lesdits moyens de pliage (28) comprenant : un corps (30) comportant une ouverture (34) avec une rainure (36) formée dans ledit corps (30) s'étendant radialement depuis ladite ouverture (34) et dans lequel, en outre, un élément coulissant (38) est positionné à l'intérieur de ladite rainure (36) pour venir en butée contre ledit côté tranchant (44) dudit athérotome (19), ledit élément coulissant (38) étant poussé contre ledit athérotome (19) pour plier ledit ballonnet (12).

11. Procédé selon la revendication 10, consistant en outre à positionner ledit côté tranchant (44) dans ladite rainure (36) en butée contre ledit élément coulissant (38) et à réaliser ladite étape de contraction en faisant coulisser ledit élément (38) vers ladite ouverture (34) afin de déplacer ledit athérotome (19) vers l'axe longitudinal dudit ballonnet (12), formant ainsi un pli dans ladite paroi (16) correspondant à l'emplacement dudit athérotome (19).

12. Procédé selon la revendication 11, dans lequel le contact entre ledit côté tranchant (44) et ledit élément (38) est amorti par une garniture élastomère (40) fixée sur ledit élément (38).

13. Procédé selon l'une quelconque des revendications 10 à 12, dans lequel ledit élément coulissant (38) est forcé vers ladite ouverture (34).

14. Procédé selon la revendication 11, dans lequel un fluide est retiré de ladite chambre (17) tout en coulissant ledit ballonnet (12).

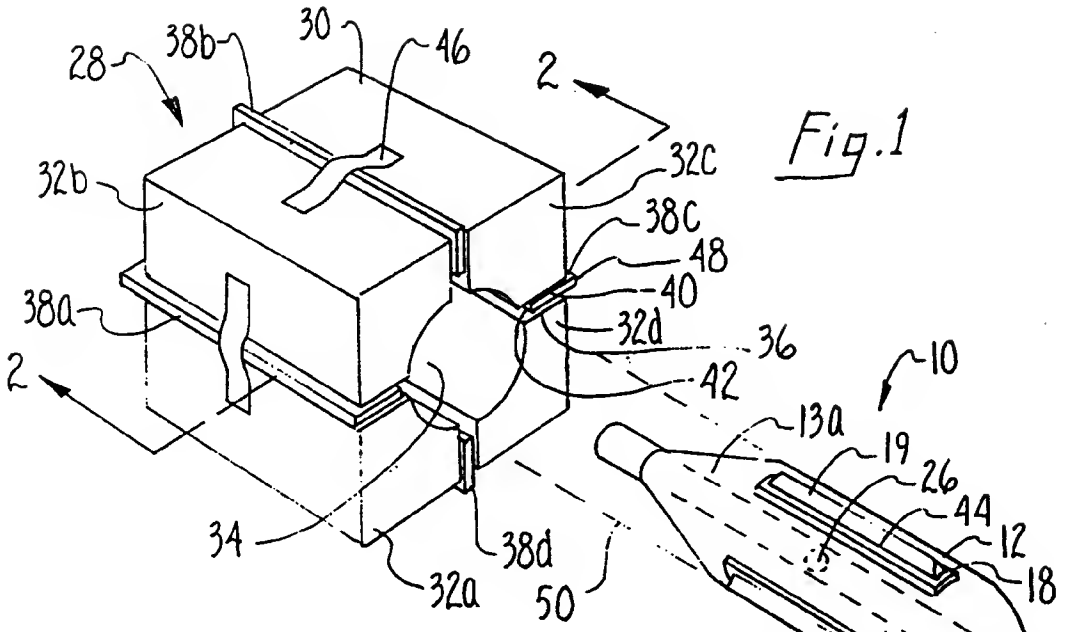

Fig.1

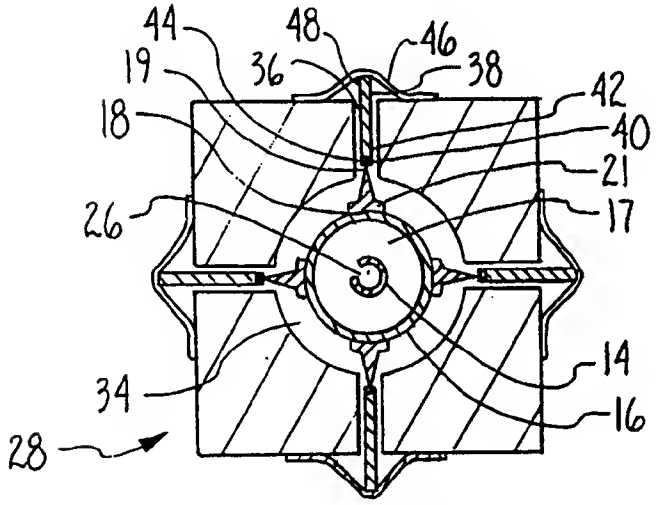

Fig.2A

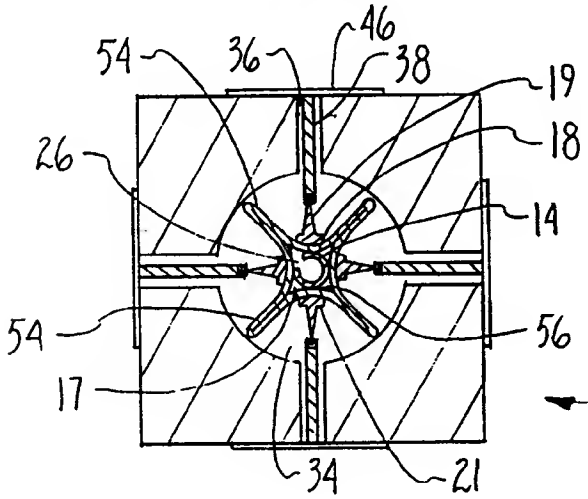

Fig.2B